NOV 22 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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TRADE NAME: Femtec Laser System for Capsulotomy

COMMON NAME: Ophthalmic Laser

CLASSIFICATION NAME: Ophthalmic Femtosecond Laser

DEVICE CLASSIFICATION: Class II

PRODUCT CODE OOE (Ophthalmic Femtosecond Laser)

PREDICATE DEVICES: LenSx 550 Laser System, LensAR Laser System for Anterior Capsulotomy

PREDICATE DEVICES:

510(K) NUMBER	PRODUCT TRADE NAME	MANUFACTURER
K082947	LenSx 550 Laser System	LenSx Lasers / Alcon
K090633	LensAR Laser System for Anterior Capsulotomy	LensAR, Inc.
K060372	IntraLase FS Laser	Abbott Medical Optics
K040204	Zyoptix XP Microkeratome	Technolas Perfect Vision GmbH
K022560	Moria 2 Microkeratome	Moria

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Description of the Device Subject to Premarket Notification:
The Femtec Laser System for Capsulotomy is a precision ophthalmic surgical laser indicated for use in patients undergoing anterior capsulotomy during cataract surgery. Capsular dissection is achieved through precise individual micro-photodisruption of tissue, measuring a few microns in diameter, created by tightly focusing ultrashort laser pulses into the targeted capsular tissue. Surgical effects are produced by scanning thousands of individual pulses, producing a continuous incision. The location of the tissue photodisruption is controlled by a fixed laser beam focused through a scanning optic system to the desired location. Pre-programmed patterns produce capsular resections of predetermined diameter and height.

Laser pulses are delivered through a sterile (disposable) Patient Interface, consisting of a contact lens and suction clip to provide suction. The contact lens and suction clip assembly creates a reference surface for depth control and fix the eye relative to the delivery of the laser beam.

Indication for Use:
The Femtec Laser System for Capsulotomy is indicated for anterior capsulotomy during cataract surgery. The proposed indication for use is identical to the previously cleared LenSx 550 Laser (K082947) and LensAR Laser System for Anterior Capsulotomy (K090633).

Technical Characteristics Comparison:
The Femtec Laser System for Capsulotomy mode of operation and technology are very similar to the previously cleared LenSx 550 Laser (K082947) and LensAR Laser System for Anterior Capsulotomy (K090633). The Femtec Laser System for Capsulotomy utilizes ultrashort, high frequency laser pulses to create photodisruption in the anterior capsule, as do the predicate devices. The Femtec Laser system utilizes a curved patient interface as does the LenSx 550 laser predicate, while the LenAR Laser System utilizes a fluid-fluid interface. However, both patient interface configurations have the same function, which to provide a reference surface through which the laser pulses are delivered to the anterior capsule and are therefore substantially equivalent.

Brief Summary of Preclinical and Clinical Performance Test Results:
Technolas Perfect Vision developed the Femtec Laser system for use in anterior capsulotomy. Pre-clinical and clinical testing has included bench testing and a prospective clinical trial.

Performance Data:
Testing and analyses included accuracy and reproducibility of capsulotomy incisions in porcine eyes, as well as in plastic and agar gel optical phantoms. The data demonstrated that the Femtec Laser System produces anterior capsulotomies that are accurate and predictable in size, shape, and centration over a range of depths. The capsular edge created by the Femtec Laser system is also at least as smooth as that created during anterior capsulotomy.

Clinical Trial:

A clinical trial of the Femtec Laser System was conducted to evaluate the performance of the laser system in the creation of anterior capsulotomy during cataract surgery. Anterior capsulotomy was successfully performed in all eyes using the Femtec Laser System; i.e., the capsulotomy was complete in all eyes, with no radial tears observed intraoperatively or postoperatively, and with an intraocular lens placed in each capsular bag. Postoperatively, the course of follow-up in the study population was unremarkable. The intraocular lens was centered in all study eyes, and no posterior capsule tears were observed. All capsulotomies were judged to be well-centered by the surgeon using visual inspection in the operating microscope. While shown to be equally safe as manual capsulorhexis, the Femtec Laser System anterior capsulotomy procedure produced significantly more circular capsulorhexis than the manual technique, and significantly more pupil-centered capsulorhexis compared to manual capsulotomy.

Basis for Determination of Substantial Equivalence:

The technological and performance characteristics of the Femtec Laser System for Capsulotomy are substantially equivalent to the technological and performance characteristics of the LenSx 550 Laser System and the LensAR Femtosecond Laser, cleared under K082947 and K090633, respectively, for anterior capsulotomy during cataract surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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NOV 2 2 2011

Re: K110427
Trade/Device Name: Femtec Laser System for Capsulotomy
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: November 7, 2011
Received: November 8, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110427

Device Name(s): Femtec Laser System for Capsulotomy

Indications for Use:

The Femtec Laser System for Capsulotomy is indicated for anterior capsulotomy during cataract surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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